

CAPRYOL 90

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
 Issue date: 10/22/2021 Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	:	Substance
Trade name	:	CAPRYOL 90
Chemical name	:	Fatty acids, C6-12, esters with propylene glycol
EC-No.	:	248-315-4
CAS-No.	:	85883-73-4
REACH registration No	:	Exempted from REACH registration (Pharmaceutical use)
Product code	:	3254
Product group	:	Trade product

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category	:	Industrial use
Use of the substance/mixture	:	pharmaceutical excipient

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

GATTEFOSSE SAS
 36 chemin de Genas CS 70070
 69804 Saint-Priest Cedex
 France
 T +33 472 22 98 00 - F +33 478 90 45 67
regulatory@gattefosse.com - www.gattefosse.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	Only for healthcare professionals
United Kingdom	National Poisons Information Service (Cardiff Centre) University Hospital Llandough	Penlan Road CF64 2XX Llandough	0344 892 0111	Only for healthcare professionals
United Kingdom	National Poisons Information Service (Edinburgh Centre) Royal Infirmary of Edinburgh	Little France Crescent EH16 4SA Edinburgh	0344 892 0111	Only for healthcare professionals
United Kingdom	National Poisons Information Service (Belfast Centre) Royal Victoria Hospital	Grosvenor Road BT12 6BA Belfast	0344 892 0111	Only for healthcare professionals

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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Multi-constituent

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Fatty acids, C6-12, esters with propylene glycol	CAS-No.: 85883-73-4 EC-No.: 248-315-4 REACH-no: Exempted from REACH registration (Pharmaceutical use)	100	Not classified

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water.

First-aid measures after eye contact : Rinse eyes with water as a precaution.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

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5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

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8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: light yellow.
Appearance	: Oily liquid.
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: > 210 °C
Flammability	: Not applicable
Explosive properties	: Product is not explosive.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: > 140 °C
Auto-ignition temperature	: > 250 °C
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: insoluble in water.

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Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50 °C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20 °C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. On burning: release of carbon monoxide - carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (No data available)
Acute toxicity (inhalation)	: Not classified (No data available)

Fatty acids, C6-12, esters with propylene glycol (85883-73-4)

LD50 oral rat	> 5003 mg/kg Data: Gattefossé;(OECD 401 method);Test item: CAPRYOL 90
Skin corrosion/irritation	: Slightly irritating to rabbits on cutaneous application. Slightly irritant but not relevant for classification (Based on available data, the classification criteria are not met)
Additional information	: Data: Gattefossé (OECD 404 method) Test item: CAPRYOL 90 and CAPRYOL PGMC
Serious eye damage/irritation	: Slightly irritating to rabbits on ocular application. Slightly irritant but not relevant for classification (Based on available data, the classification criteria are not met)
Additional information	: Data: Gattefossé (OECD 405 method) Test item: CAPRYOL 90 and CAPRYOL PGMC
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)

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Additional information	: Source: European Chemicals Agency, http://echa.europa.eu/ (OECD 406 method) Results obtained on a similar product: CAS 37321-62-3 Dodecanoic acid, ester with 1,2-propanediol
Germ cell mutagenicity	: Mutagenicity : Ames test : negative
Additional information	: Data: Gattefossé (OECD 471 method) Test item: CAPRYOL 90 and CAPRYOL PGMC
Carcinogenicity	: Not classified (Based on lack of available data, it is not possible to provide classification)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)

Fatty acids, C6-12, esters with propylene glycol (85883-73-4)

NOAEL (animal/female, F0/P)	> 2500 Data: Gattefossé; Maternal toxicity - gavage to pregnant rats from gestation days 6-17; Test item: CAPRYOL 90
NOAEL (animal/female, F1)	> 2500 Data: Gattefossé; embryo/fetal developmental toxicity - gavage to pregnant rats from gestation days 6-17; Test item: CAPRYOL 90

STOT-single exposure	: Not classified (Based on lack of available data, it is not possible to provide classification)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)

Fatty acids, C6-12, esters with propylene glycol (85883-73-4)

NOAEL (subacute, oral, animal/male, 28 days)	> 2500 mg/kg bodyweight Data: Gattefossé; Test item: CAPRYOL 90
Aspiration hazard	: Not classified (Based on lack of available data, it is not possible to provide classification)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (No ecotoxicological data about this product are known)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (No ecotoxicological data about this product are known)
Additional information	: No data available.

12.2. Persistence and degradability

Persistence and degradability	Readily biodegradable.
Source	European Chemicals Agency, http://echa.europa.eu/
Results obtained on a similar product	ECHA registration dossier: CAS 37321-62-3 (Dodecanoic acid, ester with 1,2-propanediol)

12.3. Bioaccumulative potential

Fatty acids, C6-12, esters with propylene glycol (85883-73-4)	
Bioaccumulative potential	Accumulation in organisms is not to be expected.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

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12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Fatty acids, C6-12, esters with propylene glycol is not on the REACH Candidate List

Fatty acids, C6-12, esters with propylene glycol is not on the REACH Annex XIV List

Fatty acids, C6-12, esters with propylene glycol is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Fatty acids, C6-12, esters with propylene glycol is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Propylene glycol caprylate is not subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration

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Abbreviations and acronyms:	
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

The classification complies with

: ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.